



**YOUNG
CONAWAY**

June 10, 2021

The Honorable Maryellen Noreika
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801

Re: PureWick Corporation v. Sage Products, LLC, C.A. No. 19-1508-MN

Dear Judge Noreika:

We represent Sage and respond to PureWick's letter (D.I. 171), which is yet another motion to prevent relevant evidence relating to PureWick's on-sale bar and prior public uses from reaching the factfinder. PureWick's latest motion is a premature *Daubert* motion that circumvents the Court's Scheduling Order's timing and page limits for *Daubert* motions and should be deferred. PureWick seeks to preclude testimony from Robert Sterne, a recognized expert on patent prosecution practice including as it relates to priority date issues. Here, the PTO found the priority date of asserted claims were August 29, 2016 (*e.g.*, Ex. 1 at _1422-23), and PureWick was publicly using and selling its product well before the critical date (Ex. F at 55-60). (*See also* Ex. A at ¶¶49, 56, 68-77, 45-64.) Sterne's report explains patent practice, how certain submissions are presented to the PTO, and what would be understood to practitioners during patent practice regarding priority claims, providing relevant background for Sage's defenses. (*Id.*, ¶¶14-15.) Contrary to PureWick's arguments, there is a crush of case law allowing such expert testimony in this District including on the very issues that are the subject of the present report. *Zimmer Surgical v. Stryker Corp.*, 365 F. Supp. 3d 466, 498 (D. Del. 2019) ("[t]o the extent that Mr. Sterne provides testimony on the opportunities for a reasonable patent attorney would have had to recognize and correct a priority claim, that testimony is permissible as it is helpful to the factfinder...."). Sterne never opined on anyone's "intent." Sterne's testimony is helpful to the trier of fact especially on the complex proceedings regarding how the PTO and practitioners handle priority. Sage should be allowed to litigate its case, and PureWick's latest attempt to eliminate relevant evidence should be rejected.

PureWick's Motion Is A Premature *Daubert* Motion That Circumvents The Page Limits

PureWick's motion violates the Scheduling Order, which states that a "*Daubert* motion to exclude or preclude all or any portion of an expert's testimony" is to be filed along with dispositive motions no "more than ten (10) days before" September 20, 2021. (D.I. 56 at 9-10.) The Order also includes the page limits for the motions. (*Id.* at 10.) In *LEO Pharma v. Actavis Labs.*, No. 16-CV-333-JFB-SRF, 2018 WL 3374094, at *2,3 (D. Del. July 11, 2018), Magistrate Judge Fallon denied a motion to strike a patent attorney report, finding that the motion was "at its core, a *Daubert* motion" that should have been filed in accordance with the Scheduling Order deadlines.¹

Here, PureWick does not dispute that its motion is based on *Daubert's* "relevance"

¹ PureWick's case, *Braun v. Terumo* (Ex. B), did not involve a motion to strike a patent law expert in contravention of a scheduling order. Rather, it involved a dispute over confidential information.

standards. And, instead of addressing the Scheduling Order, PureWick ignored it. But the Order has timing and page limit requirements, and PureWick's circumvention of the Order requires Sage and the Court to address *Daubert* issues twice (and, now, without the proper context, *see n.2*) while also disrupting Sage's preparation of expert reports. PureWick's only argument for its violation—that it would be “expensive” to respond—is not a valid basis for ignoring this Court's Order. First, PureWick is not compelled to respond and can instead file a *Daubert* motion at the appropriate time. Second, the argument would hold true for any report subject to a *Daubert* challenge and thus would render every Scheduling Order meaningless.² Third, only weeks ago, PureWick insisted on proceeding on potentially irrelevant expert reports when it came to Sage's request to stay those issues and avoid expenses. (D.I. 142 at 4-5.) The Court found that the parties should proceed with expert discovery despite the expense to Sage and even though it may later prove unnecessary. (5/4/21 Minute Entry.) Fourth, PureWick has not moved for a stay (as Sage did) nor proven any of the relevant stay factors.

Sterne's Testimony Is Standard in Patent Cases And Would be Helpful to the Fact Finder

Contrary to PureWick's outdated and off-point law, this District has recognized that *patent attorney “experts are frequently permitted to testify about matters such as general practices and procedures employed by the PTO in examining...patents.”* *Sonos v. D & M Holdings*, 297 F. Supp. 3d 501, 511 (D. Del. 2017). That is exactly what Sterne is testifying about. Sterne's testimony on “practice and procedures at the Patent Office,...including priority claims” and “reasonable practices for an attorney in the field of patent practice” is relevant to invalidity and is helpful background for the factfinder. (Ex. A, ¶¶14-15, 4.) PureWick admits that patent prosecution practices, the prosecution history, and priority dates are at issue. Sterne's 40+ years of experience qualifies him to testify on those subjects. (¶¶6-12.)

Indeed, recent law from this District acknowledges that “PTO procedures are generally foreign to the average person Certainly it may be helpful ‘to hear someone experienced in those procedures explain how they operate in terms that a layperson can understand.’” *Shire Viropharma v. CSL Behring*, No. 17-CV-414-MSG, 2021 WL 1227097, at *18 (D. Del. Mar. 31, 2021); *see also W.L. Gore v. C.R. Bard*, No. 11-515-LPS, 2015 WL 12815314, at *4 (D. Del. Nov. 20, 2015) (“the Court will permit...proposed testimony regarding general PTO practice and procedure...the Court will likewise permit...summary of the prosecution history of the asserted patents”). This is also the routine practice of other courts. *See Novartis v. Teva Pharms.* No. 05-CV-1887 DMC, 2009 WL 3754170, at *7 (D.N.J. Nov. 5, 2009) (permitting testimony on “PTO practices and procedures”); *Szoka v. Woodle*, No. 02-5524, 2004 WL 5512964, at *3 (N.D. Cal. June 7, 2004) (“courts have regularly permitted expert testimony by patent attorneys on a range of issues”).

Mr. Sterne is not a “legal expert” providing opinions on patent law nor is he offering opinions on anyone's “intent” or “state of mind;” rather, *Sterne's report focuses on patent practices in the PTO* (*see, e.g.*, Ex. A, ¶¶ 17-37, 48-58), which is permitted and helpful.³ *Trading*

² Sage has identified multiple problems with PureWick's reports that will be the subject of future *Daubert* motions including PureWick experts that offered opinions on intent and state of mind.

³ The *Lannett*, *AstraZeneca*, *Boehringer*, and *Ondeo* cases cited by PureWick did not involve patent attorneys opining on patent procedures or priority, but rather opinions on patent law, what persons “knew,” what the PTO thought, or regurgitating the file history. And PureWick's *Brigham*

Techs. Int'l v. eSpeed, 595 F.3d 1340, 1360 (Fed. Cir. 2010) (attorney who offered “general opinions on patent practices...did not usurp the district court’s role of instructing the jury on the law.”). Here, Sterne does not proffer improper legal conclusions (and PureWick cites none); rather, Sterne’s testimony is “helpful to hear [a] case-specific summary of what was filed when in context with [the expert’s] discussion of general PTO procedures that relate to such filings.” *Gore, supra* at *4. Statements about patent procedures are not intent testimony, and it is patent practitioners who should explain those procedures to the fact finder, not technical experts, as the case law shows.

Moreover, courts have specifically recognized that testimony relating to priority issues are helpful. Indeed, Mr. Sterne has already been permitted to opine in this District on PTO practices and procedures including as it relates to priority. In *Zimmer*, 365 F. Supp. 3d 466, 498, Judge Andrews stated: “Mr. Sterne provides testimony on the opportunities for a reasonable patent attorney would have had to recognize and correct a priority claim, that testimony is permissible as it is helpful to the factfinder to evaluate the deposition testimony from Zimmer’s prior patent counsel.”⁴ In the instant case, Sterne’s expert report provides the same, relevant testimony from the perspective of a reasonable patent attorney that is equally as helpful as it was to the trier of fact in *Zimmer*. (See, e.g., Ex. A at ¶¶14, 35-58, 65-77.) See also *Bone Care v. Pentech Pharms., Inc.*, No. 08-CV-1083, 2010 WL 3928598, at *14 (N.D. Ill. Oct. 1, 2010) (“testimony relating to the patent application process, the operations and functions of the PTO, and the criteria to which examiners look in assessing patentability (including obviousness, priority, etc.) are based in [expert’s] specialized knowledge and touch on the core issues of the case.”

Contrary to PureWick’s claims, ***opinions from the perspective of a “reasonable patent attorney” are permitted and helpful.*** Judge Andrews allowed Sterne testimony from the perspective of “a reasonable patent attorney” and such testimony is common. *Zimmer*, 365 F. Supp. 3d at 498; *Reiffin v. Microsoft*, 270 F. Supp. 2d 1132, 1146 (N.D. Cal. 2003) (permitting testimony that “actions during the prosecution were in accord with what a competent patent attorney reasonably would have done”); *In re Namenda Antitrust Litig.*, 331 F. Supp. 3d 152, 184–85 (S.D.N.Y. 2018) (permitting testimony regarding “what a reasonable and competent patent attorney would have advised the litigants”). And PureWick is wrong when it states “the patent ‘industry’ is the province of the Court.” Experts are the ones who opine on “industry standards.” *Inline Conn. v. AOL Time Warner*, 472 F. Supp. 2d 604, 608 (D. Del. 2007) (allowing testimony on industry standards); *Zimmer*, 365 F. Supp. 3d at 501 (testimony on “standard practices”).

Finally, Mr. Sterne’s opinions are also relevant to Sage’s exceptional case allegations—that, e.g., a reasonable patent attorney would have investigated PureWick’s sales and uses of its covered products made before the PTO’s determined priority date (e.g., ¶¶68-78). See *Abbott Biotechnology Ltd. v. Centocor Ortho Biotech, Inc.*, No. 09-40089-FDS, 2014 WL 7330777, at *7 (D. Mass. Dec. 19, 2014); *Zimmer*, 365 F. Supp. 3d at 500 (allowing testimony to contextualize accused infringer’s actions). Those theories were clearly disclosed. (Ex. F at 76-77, 55-60.)

Mr. Sterne’s testimony is of the type routinely allowed; it should be allowed here.

case allowed testimony “to the extent that it explains the PTO’s practices and procedures,” while *Sundance* recognized “patent office practice and procedure” testimony could be useful.

⁴ PureWick’s claim that Judge Andrews “struck much of Sterne’s report” is baseless. *Id.*

Respectfully,

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)

Enclosure (Exhibit 1) (cited Exs. A, B, and F enclosed with PureWick letter (D.I. 171)

cc: All Counsel of Record (via E-Mail)